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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,028

03/24/2005

Sarina Striem

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9002

23280

7590

12/26/2007

DAVIDSON, DAVIDSON & KAPPEL, LLC

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NEW YORK, NY 10018

EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

12/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/529,028

Applicant(s)

STRIEM ET AL.

Examiner

Taylor Victor Oh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,11-15,17-23,26-28,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-2,5-9,1-15,17-23,26-28,30-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Lack of Unity***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, and 5-8, drawn to a method of inhibiting protease activity using the formula (I);

Group II, claim(s) 9, and 11-15, drawn to a method for preventing, or treating a MMP-related diseases using the formula (I);

Group III, claim(s) 17-18, drawn to drawn to a method for preventing, or treating a cancer using the formula (I);

Group IV, claim(s) 19-23, and 26, drawn to a method for treating angiogenesis dependent Disease using the formula (I);

Group V, claim(s) 27-28, and 30-31, drawn to a method for preparation of a medicament using the formula (I); and its pharmaceutical composition and compounds.

I. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (" requirement of unity of invention ").

PCT Rule 13.2 states " Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression " special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In the instant case, the invention of Group I is directed to the method of inhibiting protease activity using the formula (I), whereas the invention of Group II is directed to the method for preventing, or treating a MMP-related diseases using the formula (I). Both may have commonly shared a compound having the formula I. However, according to Gordon et al (US 5,776,933), it shows that aminediol compounds with an inhibiting protease activity have chemically different structures from the commonly shared compounds of formula (I) between them. From this, there is no the special technical feature between Groups I and II. Thus, there is no single general inventive

concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the method of inhibiting protease activity using the formula (I), whereas the invention of Group III is directed to the method for preventing, or treating a cancer using the formula (I). Both may have commonly shared a compound having the formula I. However, according to Gordon et al (US 5,776,933), it shows that aminediol compounds with an inhibiting protease activity have chemically different structures from the commonly shared compounds of formula (I) between them. From this, there is no the special technical feature between Groups I and III. Thus, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the method of inhibiting protease activity using the formula (I), whereas the invention of Group IV is directed to the method for treating angiogenesis using the formula (I). Both may have commonly shared a compound having the formula I. However, according to Gordon et al (US 5,776,933), it shows that aminediol compounds with an

inhibiting protease activity have chemically different structures from the commonly shared compounds of formula (I) between them. From this, there is no the special technical feature between Groups I and IV. Thus, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

In the instant case, the invention of Group I is directed to the method of inhibiting protease activity using the formula (I), whereas the invention of Group V is directed to method for preparation of a medicament using the formula (I) and its pharmaceutical composition and compounds.

Both may have commonly shared a compound having the formula I. However, according to Gordon et al (US 5,776,933), it shows that aminediol compounds with an inhibiting protease activity has chemically different structures from the commonly shared compounds of formula (I) between them. From this, there is no the special technical feature between Groups I and V. Thus, there is no single general inventive concept and no unity of invention for the method or the process as defined in 37 CFR 1.475.

37 CFR 1.475 states that a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories:

- a. A product and a process specially adapted for the manufacture of said product;
- or

- b. A product and a process of use of said product; or
- c. A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- d. A process and an apparatus or means specially designed for carrying out the said process; or
- e. A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

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record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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TAYLOR VICTOR OH  
PRIMARY EXAMINER

12/18/07